



## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Aoki et al.

Confirmation No.8682

Serial No.: 10/630,604

Group Art Unit: 1656

Filed: July 29, 2003

Examiner: KAM, Chih Min

**Title: BURN PAIN TREATMENT BY PERIPHERAL ADMINISTRATION OF A NEUROTOXIN**

**Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**

**DECLARATION UNDER 37 C.F.R. § 1.131**

1. I am the attorney of record for the above identified pending U.S. patent application 10/630,604. I am employed by Allergan, Inc., the assignee of this application.
2. I have personal knowledge of the matters set forth herein and could and would testify to these matters before the United States Patent and Trademark Office if required to do so.
3. On a date prior to April 7, 2000, I received an email, a true and correct copy of which is attached hereto as Exhibit A. The date of the receipt of the Exhibit A email has been redacted. Attached as Exhibit B is a true and correct copy of page 32 of the draft patent application which was attached to the Exhibit A email. The patent application was filed with the United States Patent and Trademark Office on April 14, 2000, as serial number 09/550,371. The present patent application serial number 10/630,604 is a continuation of patent application serial number 10/199,222, filed July, 18, 2002, which is a continuation patent application of serial number 09/550,371, filed April 14, 2000.

Hence, the specification of this patent application serial number 10/630,604 is identical to the specification of parent patent application 09/550,371 filed April 14, 2000.

4. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like are punishable by fine, imprisonment, or both under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: September 7<sup>th</sup>, 2006

Stephen Donovan  
Stephen Donovan

Attachments: Exhibits A and B.



**Donovan\_Stephen**

---

**From:** Quan [qln@patlawyers.com]  
**Sent:**  
**To:** Stephen Donovan  
**Subject:** peripheral admin of botox/pain  
**Attachments:** 2880mod\_app.doc

Dear Stephen,

Attached is the revised application. I am also faxing you Figures 1 and 2. I did not include the graph marked as page 7 from the package you sent me because it is repetitive of Figure 1.

Quan



SEP 08 2006

A patient, age 45, presents with inflammatory pain in the chest region. The patient is treated by a bolus injection of between about 0.05 U/kg to about 2 U/kg of a neurotoxin, preferably botulinum toxin type A, intramuscularly to the chest. The particular dose as well as the frequency of administrations depends upon a variety of factors within the skill of the treating physician, as previously set forth. Within 1-7 days after neurotoxin administration the patient's pain is substantially alleviated. The duration of the pain alleviation is from about 7 to about 27 months.

Example 6

10 Peripheral Administration of a Neurotoxin to Treat Laceration Pain

A patient, age 39, experiencing pain subsequent to a laceration on the index finger. The patient is treated by a bolus injection of between about 0.05 U/kg to about 2 U/kg of a neurotoxin, preferably botulinum toxin type A, subcutaneously to the site of laceration. The particular dose as well as the frequency of administrations depends upon a variety of factors within the skill of the treating physician, as previously set forth. Within 1-7 days after neurotoxin administration the patient's pain is substantially alleviated. The duration of the pain alleviation is from about 7 to about 27 months.

20 Example 7

Peripheral Administration of a Neurotoxin to Treat Pain Caused by Burns

A patient, age 51, experiencing pain subsequent to a first or second degree burn to the arm. The patient is treated by a bolus injection of between about 0.05 U/kg to about 2 U/kg of a neurotoxin, preferably botulinum toxin type A, subcutaneously to the arm. The particular dose as well as the frequency of administrations depends upon a variety of factors within the skill of the treating physician, as previously set forth. Within 1-7 days after neurotoxin administration the patient's pain is substantially alleviated. The duration of the pain alleviation is from about 7 to about 27 months.